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10/562,195	12/23/2005	Steven Walter Clavey	50438/002001	4118

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

CLARK, AMY LYNN

ART UNIT	PAPER NUMBER
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1655

NOTIFICATION DATE	DELIVERY MODE
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11/26/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary

Application No.

10/562,195

Applicant(s)

CLAVEY, STEVEN WALTER

Examiner

Amy L. Clark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 August 2007.
- 2a) This action is **FINAL**.
- 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
4a) Of the above claim(s) 3-9, 13, 14 and 16-25 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1, 2, 10-12 and 15 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/23/2005.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group 1, claims 1-15 and the election of specie A in the reply filed on 24 August 2007 is acknowledged.

Claims 1-25 are currently pending.

Claims 3-9, 13, 14 and 16-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on BBB.

Claims 1, 2, 10-12 and 15 are currently under examination.

Claim Objections

Claims 1 and 2 are objected to because of the following informalities: wherever Applicant provides a Latin name for a plant or herb, Applicant must italicize the entire name and must capitalize the genus name and write the species name in lower-case. For example, in claim 1, line 3, Applicant provides the Latin name, "Paeonia Obovata", please correct this name to read *Paeonia obovata* and do the same for all other Latin names. It is also suggested that Applicant correct the claims such as this example provided for an acceptable way to correct claim 1, "A composition for treating or alleviating ~~a symptom resulting from a gynecological disorder~~ (please put in the specific condition to be treated), comprising the herbs: Chi Shao (~~Paeonia Obovata~~ *Paeonia obovata*), Root) root, Dang Gui (~~Angelica Polymorpha~~ *Angelica polymorpha*), Root) root,

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Chuan Xiong (~~Ligusticum Wallichii~~, Ligusticum wallichii-Root) root, Xiang Fu (~~Cyperus Rotundus~~, Cyperus rotundus Rhizome) rhizome, Yah Hu Suo (~~Corydalis turtschaninovii~~, Rhizome) rhizome and Tao Ren (~~Prunus persica~~, Seed) seed, or parts thereof."

Appropriate correction is required.

Claim 12 is objected to because of the following informalities: please correct "flavours, colourings" in lines 2 and 3 to read flavors, colorings. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 10-12 and 15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for treating gynecopathy comprising Chi Shao (*Paeonia obovata*) root, Dang Gui (*Angelica polymorpha*) root, Chuan Xiong (*Ligusticum wallichii*) root, Xiang Fu (*Cyperus rotundus*) rhizome, Yah Hu Suo (*Corydalis turtschaninovii*) rhizome and Tao Ren (*Prunus persica*) seed, and while also being enabling for a composition for treating symptoms of endometriosis and for treating the side effects of Danocrine™ comprising Fu Ling (*Poria cocos*, Sclerotium) in an amount of 12 g, Ze Xie (*Alisma plantago-aquatica*, Rhizome) in an amount of 15 g, Dang Gui (*Angelica polymorpha*, Radix) in an amount of 12 g, Bai Zhu (*Atractylodes macrocephala*, Rhizoma) in an amount of 12 g, Xiang Fu (*Cyperus*

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rotundus, Rhizome) in an amount of 12 g, Yan Hu Suo (*Corydalis turtschaninovii*, Rhizome) in an amount of 12 g, Gan Cao (*Glycyrrhizae uralensis*, Radix) in a amount of 3 g, He Huan Pi (*Albizzia julibrissin*, bark) in an amount of 15 g, Yu Jin (*Curcumae*, Tuber) in an amount of 12 g, Ren Dong Teng (*Lonicerae Japonicae*), Ramus in an amount of 18 g, Chuan Lian Zi Meliae Toosendan, Fructus 12 g Fo Shou Pian Citrii Sarcodactylis, Fructus 6 g Ban Xia (*Pinelliae Ternata*), Rhizome an amount of 12 g, Shi Chang Pu (*Acori Graminei*, Rhizoma) in an amount of 12 g, Shen Qu (*Massa Fermentata*) in an amount of 15 g , wherein the composition is administered in an amount of 100 mls of decoction in the morning and evening followed by a composition comprising: Chi Shao (*Paeonia obovata*, Radix) in an amount of 9 g, Bai Shao (*Paeonia lactiflora*, Radix) in an amount of 9 g, Fu Ling (*Poria cocos*, Sclerotium) in an amount of 15 g, Ze Xie (*Alisma plantago-aquatica*, Rhizoma) in an amount of 12 g, Dang Gui (*Angelica polymorpha*, Radix) in an amount of 12 g, Bai Zhu (*Atractylodes macrocephala*, Rhizome) in an amount of 15 g, Chuan Xiong (*Ligusticum wallichii*, Radix) in an amount of 12 g, Xiang Fu (*Cyperus rotundus*, Rhizoma) in an amount of 12 g Yan Hu Suo *Corydalis turtschaninovii*, Rhizoma 2 g Gan Cao *Glycyrrhiza uralensis*, Radix 3 g He Huan Pi *Albizzia julibrissin*, bark 15 g Chai Hu *Bupleurum falcatum*, Root 6 g Chen Pi *Citrus Reticulata*, pericarpium 6 g Fo Shou Pian Citrii *Sarcodactylis*, Fructus 6 g Chuan Lian Zi *Meliae Toosendan*, Fructus 9 g Hong Teng *Caulis Sargentodoxae Cuneatae* 18 g Gui Zhi *Cinnamomi Cassiae*, Ramulus 9 g, does not reasonably provide enablement for a composition for treating or alleviating a symptom resulting from a gynecological disorder, comprising the herbs: Chi Shao (*Paeonia*

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obovata, Root), Dang Gui (Angelica Polymorpha, Root), Chuan Xiong (Ligusticum Wallichii, Root), Xiang Fu (Cyperus Rotundus, Rhizome), Yah Hu Suo (Corydalis turtschaninovii, Rhizome) and Tao Ren (Prunus persica, Seed), or parts thereof.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Enablement is considered in view of the *Wands* factors (MPEP 2164.01(A)).

These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art predictability of the art and the amount of experimentation necessary. All of the *Wands* factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: The claims are drawn to a composition for treating or alleviating a symptom resulting from a gynecological disorder, comprising the herbs: Chi Shao (Paeonia obovata, Root), Dang Gui (Angelica Polymorpha, Root), Chuan Xiong (Ligusticum Wallichii, Root), Xiang Fu (Cyperus Rotundus, Rhizome), Yah Hu Suo (Corydalis turtschaninovii, Rhizome) and Tao Ren (Prunus persica, Seed), or parts thereof.

Breadth of the Claims: The claims are broad in that a composition comprising the herbs: Chi Shao (Paeonia obovata, Root), Dang Gui (Angelica Polymorpha, Root), Chuan Xiong (Ligusticum Wallichii, Root), Xiang Fu (Cyperus Rotundus, Rhizome), Yah

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Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof may be administered to treat or alleviate a symptom resulting from a gynecological disorder, in a patient. The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

Guidance of the Specification and Existence of Working Examples: The specification describes a composition for treating the symptoms of endometriosis and for treating the side effects of Danocrine™ comprising Fu Ling (*Poria cocos*, Sclerotium) in an amount of 12 g, Ze Xie (*Alisma plantago-aquatica*, Rhizome) in an amount of 15 g, Dang Gui (*Angelica polymorpha*, Radix) in an amount of 12 g, Bai Zhu (*Atractylodes macrocephala*, Rhizoma) in an amount of 12 g, Xiang Fu (*Cyperus rotundus*, Rhizome) in an amount of 12 g, Yan Hu Suo (*Corydalis turtschaninovii*, Rhizome) in an amount of 12 g, Gan Cao (*Glycyrrhizae uralensis*, Radix) in a amount of 3 g, He Huan Pi (*Albizzia julibrissin*, bark) in an amount of 15 g, Yu Jin (*Curcumae*, Tuber) in an amount of 12 g, Ren Dong Teng (*Lonicerae Japonicae*), Ramus in an amount of 18 g, Chuan Lian Zi Meliae Toosendan, Fructus 12 g Fo Shou Pian Citrii Sarcodactylis, Fructus 6 g Ban Xia (*Pinelliae Ternata*), Rhizome an amount of 12 g, Shi Chang Pu (*Acori Graminei*, Rhizoma) in an amount of 12 g, Shen Qu (*Massa Fermentata*) in an amount of 15 g, wherein the composition is administered in an amount of 100 mls of decoction in the morning and evening followed by a composition comprising: Chi Shao (*Paeonia obovata*, Radix) in an amount of 9 g, Bai Shao (*Paeonia lactiflora*, Radix) in an amount of 9 g, Fu Ling (*Poria cocos*, Sclerotium) in an amount of 15 g, Ze Xie (*Alisma plantago-aquatica*, Rhizoma) in an amount of 12 g, Dang Gui (*Angelica polymorpha*, Radix) in an

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amount of 12 g, Bai Zhu (*Atractylodes macrocephala*, Rhizome) in an amount of 15 g, Chuan Xiong (*Ligusticum wallichii*, Radix) in an amount of 12 g, Xiang Fu (*Cyperus rotundus*, Rhizoma) in an amount of 12 g Yan Hu Suo *Corydalis turtschaninovii*, Rhizoma 2 g Gan Cao *Glycyrrhiza uralensis*, Radix 3 g He Huan Pi *Albizia julibrissin*, bark 15 g Chai Hu *Bupleurum falcatum*, Root 6 g Chen Pi *Citrus Reticulata*, pericarpium 6 g Fo Shou Pian *Citrii Sarcodactylis*, Fructus 6 g Chuan Lian Zi *Meliae Toosendan*, Fructus 9 g Hong Teng *Caulis Sargentodoxae Cuneatae* 18 g Gui Zhi *Cinnamomi Cassiae*, Ramulus 9 g, does not reasonably provide enablement for a composition for treating or alleviating a symptom resulting from a gynecological disorder, comprising the herbs: Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof.

The specification envisions that a composition comprising Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof will have utility in humans to treat or alleviate a symptom resulting from a gynecological disorder.

However, no working examples are provided with regard to a composition comprising Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah

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Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof to treat or alleviate a symptom resulting from a gynecological disorder. Furthermore, no working examples are provided that demonstrate the efficacy of a composition comprising Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof to treat or alleviate a symptom resulting from a gynecological disorder.

Predictability and State of the Art: The state of the art at the time the invention was made was unpredictable and underdeveloped. For example, genital herpes is regarded by the NIH (NICHD) as a gynecological disorder and has many unpleasant symptoms and side-effects, such as lesions or sores, pain and systemic illness. Stanberry et al. (U) teaches that for many patients with first-episode genital herpes that the first-episode is associated with severe symptoms, such as pain and systematic illness and that the severity of the disease cannot be predicted at first presentation. Stanberry further teaches that treatment of the symptoms of herpes are oral, such as with the oral medication, acyclovir, which is administered five times a day, but that if oral treatment is ineffective, that the medication may be administered intravenously. Stanberry further teaches that treating the first episode helps the patient overcome the initial symptoms but those with genital herpes are likely to have recurrences and that the therapies administered for treatment of the first episode does not affect the frequency or severity of recurrences (See page 6, "Treatment of the first episode").

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Since it appears that genital lesions and other symptoms arising from a genital herpes infection are difficult to treat, it is not clear that the claimed composition would have this effect, particularly since the specification does not provide any working examples.

Gormley (V) teaches that despite an ever increasing volume of literature on outcomes of surgical correction of stress urinary incontinence, the question regarding which procedure has the best outcome is still not answered. Please note that stress urinary incontinence is a symptom resulting from a gynecological disorder and that since urinary incontinence appears to be currently only treatable by surgery, and that the best surgical procedure for treating this symptom is still not known, it is not clear that the claimed composition would have this effect, particularly since the specification does not provide any working examples.

Thus, while the claim-designated method may be useful for providing such an effect, Applicant does not disclose a composition comprising the herbs: Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof may be administered to treat or alleviate a symptom resulting from a gynecological disorder. The Office further notes that while the specification discloses that the claim designated composition will have utility in humans to treat or alleviate a symptom resulting from a gynecological disorder, nowhere in the specification or in the limitations does Applicant direct the claimed subject matter to the administration of a composition comprising the herbs: Chi Shao (*Paeonia obovata*, Root), Dang Gui

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(*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof may be administered to any subject.

Amount of Experimentation Necessary: The quantity of experimentation necessary to carry out the claimed invention is high, as the skilled artisan could not rely on the prior art or instant specification to teach how to make and use a composition comprising the herbs: Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof to treat or alleviate a symptom resulting from a gynecological disorder in humans. In order to carry out the claimed invention, one of ordinary skill in the art would have to identify a composition comprising the herbs: Chi Shao (*Paeonia obovata*, Root), Dang Gui (*Angelica Polymorpha*, Root), Chuan Xiong (*Ligusticum Wallichii*, Root), Xiang Fu (*Cyperus Rotundus*, Rhizome), Yah Hu Suo (*Corydalis turtschaninovii*, Rhizome) and Tao Ren (*Prunus persica*, Seed), or parts thereof that can be administered in a therapeutically effective dose with an acceptable level of side-effects.

In view of the breadth of the claims and the lack of guidance provided by the specification as well as the unpredictability of the art, the skilled artisan would have required an undue amount of experimentation to make and/or use the claimed invention. Therefore, Claims 1, 2, 10-12 and 15 are not considered to be fully enabled by the instant specification.

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Please note that the main enablement issue is that Applicant is claiming that the instantly claimed composition can treat or alleviate a symptom resulting from a gynecological disorder. There are many symptoms that arise from many different types of gynecological disorders, as discussed above (such as lesions or sores, pain and systemic disease which are symptoms of genital herpes, which is a gynecological disease, and urinary incontinence, which is a symptom of a gynecological disease, such as menopause). Therefore, Applicant should consider the scope disclosed within the originally filed specification and make amendments to the claims accordingly. Also, another issue is that Applicant is claiming specific plants and their specific parts next to the specific herbs but then says, "or parts thereof" in line 8 of claim 1. Applicant is directed to the specification to pick and choose the specific plant parts used in Applicant's invention and to determine what composition of these specific plant parts is enabled by Applicant's originally filed specification.

Please further note that the art rejection provided below is with regards to a different intended use, so despite the fact that the art teaches a composition for treating gynecological conditions, such as female sterility, by administering compositions comprising the claim designated ingredients and not a composition for treating or alleviating a symptom resulting from a gynecological disorder, the art still teaches the claimed composition.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 10-12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the herbs" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 10-12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gong et al. (N, CN 1303689 A, Abstract only), in view of Cai (O, CN 1223119 A, Abstract only), Li et al. (P, CN 1074611 A, Abstract only), Zhang (Q, CN 1240143 A, Abstract only), Jenkins et al. (W, "Packaging Drugs and Pharmaceuticals") and Beckman (X, "Pharmacology: The Nature, Action and Use of Drugs").

Gong teaches a Chinese medicine preparation for curing gynecopathy, which is defined as any of various diseases occurring in women, comprising cyperus rotundus root (which is synonymous with *Cyperus rotundus* rhizome), Chinese angelica root (which is synonymous with *Angerica polymorpha* root), ligusticum root (which is

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synonymous with *Ligusticum wallichii* root), corydalis tuber (which is synonymous with *Corydalis turtschaninovii* rhizome) and licorice (which is synonymous with *Glycyrrhiza uralensis*), which reads on claim 10, since the plant itself inherently contains extracts.

Gong does not teach a composition comprising Chi Shao (*Paeonia obovata*) root, Dang Gui (*Angelica polymorpha*) root, Chuan Xiong (*Ligusticum wallichii*) root, Xiang Fu (*Cyperus rotundus*) rhizome, Yah Hu Suo (*Corydalis turtschaninovii*) rhizome and Tao Ren (*Prunus persica*) seed. However, Cai teaches an oral Chinese medicine for curing gynecopathy, such as the diseases of irregular menstruation, menstrual molimen and female sterility, which are all diseases occurring in women, comprising red peony root (which is synonymous with *Paeonia obovata* root), Chinese angelica root (which is synonymous with *Angerica polymorpha* root), nutgrass flatsedge rhizome (which is synonymous with *Cyperus rotundus* rhizome), corydalis tuber (which is synonymous with *Corydalis turtschaninovii* rhizome) and licorice (which is synonymous with *Glycyrrhiza uralensis*), which reads on claim 10, since the plant itself inherently contains extracts.

Li teaches a medicine for obstruction of woman's oviduct containing Chinese angelica (which is synonymous with *Angerica polymorpha*), red peony (which is synonymous with *Paeonia obovata*) and peach seed (which is synonymous with *Prunus persica* seed).

Zhang teaches a Chinese medicine in the form of an oral liquor for treating female infertility comprising peach kernel (which is synonymous with *Prunus persica* seed), Chinese angelica root (which is synonymous with *Angerica polymorpha* root),

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ligusticum root (which is synonymous with *Ligusticum wallichii* root), cyperus root (which is synonymous with *Cyperus rotundus* rhizome), and fennel fruit, wherein an extract is obtained by pulverizing, decocting and filtering the ingredients, which reads on pharmaceutically acceptable extracts (claim 12), which reads on claim 10, since the plant itself inherently contains extracts.

Gong does not teach a composition in the form of a liquid; however, Jenkins teaches that oral liquids have the advantage over solids of being easier to swallow and over tablets of having more rapid bioavailability (See page 59, "Oral liquids").

Beckman teaches that the way in which a drug is administered influences the effects achieved and that there are many factors in determining the appropriate form of administration (See page 38, "Route of Administration").

Therefore, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the composition taught by Gong to provide the instantly claimed invention because at the time the invention was made, the ingredients claimed by Applicant were known to be useful for the same purpose

It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been

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individually taught in prior art. Therefore, since each of the references teach Chi Shao (*Paeonia obovata*) root, Dang Gui (*Angelica polymorpha*) root, Chuan Xiong (*Ligusticum wallichii*) root, Xiang Fu (*Cyperus rotundus*) rhizome, Yah Hu Suo (*Corydalis turtschaninovii*) rhizome and Tao Ren (*Prunus persica*) seed are effective ingredients in compositions for treating gynecopathy, such as female infertility, it would have been obvious to combine these plants with the expectation that such a combination would be effective in treating gynecopathy. Thus, combining them flows logically from their having been individually taught in prior art.

It is noted that the references do not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ

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430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Therefore, it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to combine the ingredients taught by Gong, Cia, Li and Zhang to provide the instantly claimed invention because the ingredients were all known in the art to have the same function effect and it would have been obvious to one of ordinary skill in the art and one would have been motivated and had a reasonable expectation of success to modify the form in which the composition is administered, as clearly taught by Jenkins and Beckman.

Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Amy L. Clark
AU 1655

Amy L. Clark
October 26, 2007

Michelle C Flood
MICHELE FLOOD
PRIMARY EXAMINER